

## REMARKS

Claims 2-11, 13-20, 22-33, and 35-72 are pending in this application. Claims 2-11, 13-20, 22-33, 35-57 are allowed. Claims 58-60, 63-64, and 68-72 are rejected. Claims 61, 62, and 65-67 are objected to. Claims 58 and 65 have been amended. Claims 71 and 72 have  
5 been cancelled. Claims 73 and 74 were newly added. The amendments to claim 58 are supported by the disclosure on page 12, lines 15-24, and page 13, lines 17-19 of the specification. The amendments to claim 65 merely rewrites claim 65 in independent form. The newly added claims 73 and 74, similar to claims 68 and 70 respectively, merely add  
10 method of treatment claims using the pharmaceutical composition of claim 65, which has been rewritten in independent form.

Reconsideration and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

**1. Claims 71 and 72 were rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement.**

Claims 71 and 72 were rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement. According to the examiner the claim language of claims 71 and 72 is such that the method of depressing the central nervous encompasses more than just seizures. Applicants submit however that it is commonly known that oxcarbazepine, and therefore also  
15 a pharmaceutical composition comprising oxcarbazepine, is a central nervous system depressant as disclosed in the specification. See for example on page 1, lines 23 to 27 and page 11, lines 24 to 25 of the specification. For this reason applicants submit that a method of treatment for depressing the central nervous system comprising administering the pharmaceutical composition comprising oxcarbazepine of the present invention is enabled.  
20 However, although applicants disagree with the examiner's reasoning, applicants have  
25 cancelled claims 71 and 72 in order to have the current application proceed.

Therefore, applicants submit that the rejection of claims 71, and 72 is moot and withdrawal of the rejection is respectfully requested.

**30 2. Claims 58-60, 63, 64, 68, 69, and 71 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Schindler, (U.S. Patent No. 3,716,640).**

Claims 58-60, 63, 64, 68, 69, and 71 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Schindler, U.S. Patent No. 3,716,640. According to the examiner a polymorph is a specific crystal form of a compound, but a pharmaceutical

composition of a polymorphic form as a non-solid no longer possesses its crystalline properties. Furthermore, the examiner asserted that applicants' arguments submitted in response to the examiner's previous office action were considered but found not persuasive. Applicants submitted that claims 58-60, 63, 64, 68, 69, and 71 encompass pharmaceutical compositions comprising oxcarbazepine forms of the invention. Pharmaceutical compositions of the invention comprise the crystalline oxcarbazepine polymorphs in solid form where their crystalline structures are retained. For example, compositions in tablet, powder, gel, capsule or suspension forms contain polymorphs as solids. Further, applicants submitted that even if polymorphic forms may be lost when absorbed into the blood, the pending claims are not directed to oxcarbazepine in blood but instead to oxcarbazepine in a pharmaceutical composition prior to absorption. The examiner asserts that applicants are not specifically claiming solid pharmaceutical compositions but pharmaceutical compositions in general.

Independent claim 58 has been amended to more clearly define the subject matter of the present invention. Applicants submit that claim 58, as amended, requires a solid pharmaceutical composition comprising crystalline oxcarbazepine. The crystalline oxcarbazepine is selected from the crystalline forms of the present invention. The crystalline forms and structures of oxcarbazepine in the pharmaceutical compositions of the present invention are therefore retained. The Schindler reference fails to disclose the crystalline oxcarbazepine forms of the present invention nor does it disclose pharmaceutical compositions comprising them. For this reason applicants submit that claim 58, as amended, is not anticipated by Schindler. Furthermore, claims 59, 60, 63, and 64 are dependent from claim 58 and claims 68, 69, and 71 are directed to administering the pharmaceutical composition of claim 58 and are thus also not anticipated by the Schindler reference by virtue of their dependency from claim 58.

Therefore, applicants submit that claims 58-60, 63, 64, 68-69 and 71 are not anticipated under 35 U.S.C. §102(b) by Schindler. Withdrawal of the rejection is respectfully requested.

**3. Claims 58-60, 63, 64, and 68-71 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Boireau et al., (U.S. Patent No. 5,658,900).**

Claims 58-60, 63, 64, and 68-71 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Boireau et al., U.S. Patent No. 5,658,900. The examiner asserts similarly to her rejection of claims 58-60, 63, 64, 68, 69, and 71 over Schindler that a polymorph is a

specific crystal form of a compound, but a pharmaceutical composition of a polymorphic form as a non-solid no longer possesses its crystalline properties. Furthermore, the examiner asserted that applicants' arguments submitted in response to the examiner's previous office action were considered but found not persuasive. In response to applicants' arguments that 5 the pharmaceutical compositions of the presently claimed invention comprise the oxcarbazepine in solid form, the examiner asserts that applicants are not specifically claiming solid pharmaceutical compositions but pharmaceutical compositions in general.

Applicants submit that for the same reasons as discussed above, claims 58-60, 63, 64, and 68-71 are not anticipated by the Boireau et al. reference, which discloses only a method 10 of treating Parkinsonian syndrome using oxcarbazepine. Independent claim 58, as amended, is directed to a solid pharmaceutical composition comprising crystalline oxcarbazepine. Therefore, the crystal structure of oxcarbazepine in this solid pharmaceutical compositions is retained. The crystalline oxcarbazepine is selected from the crystalline forms of the present 15 invention. Moreover, the Boireau et al. reference fails to state the type of oxcarbazepine polymorph used. Furthermore, the Boireau et al. reference fails to disclose any process for preparing the oxcarbazepine polymorphs, nor does it provide any examples relating to such preparation. Boireau et al. only cites to EP 50,589, which is published in German. Examples 1-3 in EP 50,589 seem to discuss only the preparation of pharmaceutical compositions, not the preparation of oxcarbazepine itself.

20 For these reasons applicants submit that claims 58-60, 63, 64, and 68-71 are not anticipated under 35 U.S.C. §102(b) by Boireau et al. Withdrawal of the rejection is respectfully requested.

#### 4. Claims 61, 62, and 65-67 were objected to.

25 Claims 61, 62, and 65-67 are objected to for being dependent upon a rejected base claim 60. According to the examiner the claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. With respect to claims 61 and 62, applicants submit that claim 60 is not anticipated by either the Schindler or Boireau et al references as set forth above. Therefore, applicants 30 respectfully request withdrawal of the objection to claims 61 and 62.

In addition, applicants have rewritten claim 65 in independent form including all of the limitations of the base claim and any intervening claims. Further, claims 66 and 67 depend from independent claim 65, as amended. Therefore, applicants respectfully request withdrawal of the objection to claims 65-67.

Further, newly added claims 73 and 74 are directed to the same methods of treatment claimed in claims 68 and 70, which methods the examiner indicated present allowable subject matter. Newly added claims 73 and 74 are directed to the use of the pharmaceutical composition of claim 65, amended as independent claim, in such methods of treatment as opposed to the pharmaceutical composition of claim 58. Applicants believe the newly added claims do not constitute new subject matter nor do they require any further searching.

5 Allowance of the newly added claims 73 and 74 is respectfully requested.

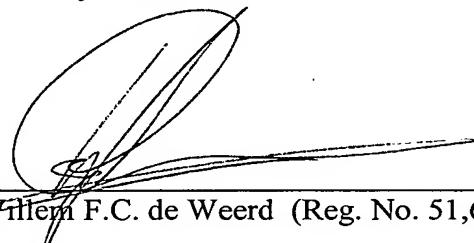
10 Applicants acknowledge and appreciate that the examiner allowed claims 2-11, 13-20, 22-32, and 35-57. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

15

Respectfully submitted,

Dated: 10/19/2006

By:

  
Willem F.C. de Weerd (Reg. No. 51,613)

20

25

Kenyon & Kenyon LLP  
One Broadway  
New York, NY 10004  
Tel: (212) 425-7000  
Fax: (212) 425-5288